

US National Stage of
PCT/ES2003/000597
ARA PINILLA et al.
Docket No: 0064-P04079US00

TRANSLATION

INTRAMEDULLARY NAIL

OBJECT OF THE INVENTION

[0001] The present invention relates to an intramedullary nail, of the type used to secure and immobilise fractures in long bones such as the femur.

[0002] The object of the invention is to achieve an elastic nail that is easier to implant in the bone, thus causing less damage thereto and improving the fixation, which also helps the bone to knit together.

BACKGROUND OF THE INVENTION

[0003] Nails are usually used to immobilise a long fractured bone, being hammered into one of the ends of the bone and having at each end a pair of holes for receiving respective cross screws that immobilise the nail by securing it to the two parts of the bone and consequently joining said fractured parts to one other.

[0004] This solution has certain problems, particularly with regard to the following aspects:

- As the bones to be immobilised are not straight, the nail tends to become deformed as it is hammered in, with the risk of passing through the bone, causing excessive damage to the spongy part thereof, which separates the intramedullary canal from the hard outer layer.
- Its fixation necessitates the use four cross screws and it is quite difficult to line up said screws with the holes in the nail.
- It is necessary to use x-rays or probe holes to locate the holes for the screws, as these are hidden inside the bone.

[0005] The difficulty of implanting said cross screws becomes considerably more pronounced in the case of the lower or distal holes, and the use of x-rays is not acceptable to surgeons, as they are frequently exposed to high radiations, particularly on their hands.

[0006] Although guiding systems exist in order to help to centre the holes, as do other systems with a "probe hole" wherein a guide is used to indicate the position of the holes in the nail, these solutions do not solve the above-described problems.

[0007] A nail called the "Marchetti" nail is known, which attempts to avoid such problems. It consists of a multiple nail, i.e. a plurality of very thin rods, which extend from a common core, so that they "open up" as they are inserted into the intramedullary canal and are driven into the spongy bone tissue, thus ensuring distal fixation without the need for distal nails.

[0008] More specifically, this set of thin rods is aided by a ring, which ascends when the nail is half inserted, opening the set of rods so that as they continue to be inserted into the intramedullary canal the thin rods point towards the spongy tissue and are driven into it.

[0009] Although this solution substantially simplifies the operating system and minimises the use of x-rays, it does present certain problems with regard to the following

- It is not very secure.
- The thin filaments or rods can damage the bone.
- The fixation is arbitrary, as the deformation and manner in which the filaments are driven into the bone is not controllable.

DESCRIPTION OF THE INVENTION

[0010] The intramedullary nail proposed by the invention successfully solves the above-described problems in each of the aspects that have been mentioned.

[0011] More specifically, to do this said nail consists of a functional combination of a nail and a probe that can move axially inside the nail, the purpose this probe being to cause a radial deformation of the nail, so that this need only be fixed by screws at the proximal end of the bone, whilst it is fixed at the distal end by said expansion effect.

[0012] This is achieved thanks to the fact that the nail itself has a plurality of filaments extending from a head at its proximal end, which are disposed according to an imaginary cylindrical surface and which converge at a node that is considerably distanced from the head, beyond which said filaments extend in a wide section, the probe including a marked protrusion close to its distal end, so that, once the nail-probe assembly has been

implanted inside the bone, as the probe moves upwards said protrusion first causes a radial deformation of the ends of the filaments, which are driven into the spongy bone tissue, and when said protrusion reaches the node of the nail, it in turn causes said node to move towards the head of the nail, which in turn causes the initial section to bulge outwards, thereby adapting and fixing the filaments to the inner wall of the bone.

[0013] In order to achieve the aforementioned effect it is necessary for the upward movement of the probe to begin before the nail has fully penetrated the bone, so that after the radial expansion of the free end of the filaments, these are driven into the bone as the nail in turn completes its final forward movement.

[0014] In accordance with the description above, it is only necessary to perform one screwing operation, namely the operation of screwing the head of the nail to the proximal end of the bone, which can be done using a complementary template, without the need for x-rays.

DESCRIPTION OF THE DRAWINGS

[0015] To complement this description and in order to aid a better understanding of the invention's characteristics, according to a preferred practical embodiment thereof, there is a set of illustrative and non-limiting drawings integral to said description, which are as follows:

[0016] Figure 1. Shows a schematic perspective view of an intramedullary nail according to the object of the present invention.

[0017] Figure 2. Shows a detail of a longitudinal section of the support for the head of the nail.

[0018] Figure 3. Shows a detail of a perspective view of the nail without its support and without the interior probe.

[0019] Figure 4. Shows a detail of a perspective view of the tool for fixing said support, in a working position at the corresponding end of the bone.

[0020] Figure 5. Shows another perspective view of the nail assembly, here duly implanted in a femur.

PREFERRED EMBODIMENT OF THE INVENTION

[0021] In view of the aforementioned figures, and particularly figure 3, it is possible to observe how the intramedullary nail proposed by the invention consists of a nail formed by a head (1) to which a plurality of rods (2) of a considerable length are joined and from which they extend, being distributed according to an imaginary cylinder of a small diameter and converging at a node (3), beyond which said rods (2) extend in terminal sections (2') of considerable length with independent free ends.

[0022] A probe (4) works with the nail (1-2), this probe consisting of a threaded rod that can be housed inside the hollow interior of the nail, having a protrusion (5) close to its distal end that acts as an expanding element for the terminal section (2') of the rods (2), as will be seen below, the threaded rod (4) emerging through the proximal end of the nail, as can be observed in figure 1.

[0023] A support (6) is solidly fixed to the bone (7) by means of screws and the nail passes therethrough, finally and immovably fixing the head thereof, for which said support (6) has a stepped axial hole (8) to receive said head (1), also having a radial fin that has a pair of holes (10) through which the respective locking screws (11) pass.

[0024] Said hole (8) in the support (6) includes a threaded section (12) at its outer end for the attachment of a collar (13) by means of which the axial traction on the probe (4) is finally performed, and which is initially used for the attachment of a tool (14), shown in figure 4, with a bent arm (15) and a pair of holes (16), so that when said tool (14) is duly attached to the support (6), the holes (16) in said tool are coaxially aligned with the holes (10) in the support (1), thus making it possible to drill holes in the bone (7) with the certainty that the screws (11) will therethrough inevitably reach the holes (10) in the support.

[0025] To assemble the nail, the support (6) is initially fixed to the proximal end of the fractured bone (7) and is screwed in place, then the assembly consisting of the probe (4) and nail (1-2) is inserted until it reaches a position in which a relative axial movement will occur between the probe (4) and the nail, giving rise to a first phase of divergence of the ends (2') of the rods (2). At that moment, an actuation on the collar (13) causes an axial traction of the probe (4) until it reaches a position in which the protrusion (5) thereon comes

into contact with the node (3) of the nail, thereby causing the terminal section (2') of the rods to adopt their maximum divergence and press against the inner wall of the bone.

[0026] At this moment, the assembly of the head (1) on the support (6) is completed until it reaches a position in which there will be a longitudinal forward movement of the nail, so that the free ends of the rods (2') are driven into the spongy bone tissue, and the proximal section (2) of said rods bulges outwards, i.e. said rods undergo a radial expansion in this area, pressing against the side wall of the bone and thus achieving not only an anti-rotational or anti-torsion tension, but also a longitudinal tension of the bone, which helps it to knit together.

[0027] The filaments that are drive into the spongy tissue are controllable and almost reach a perpendicular position relative the bone, which gives the nail greater stability.

[0028] The elastic properties of the nail generate longitudinal tension when the patient puts weight on the leg, thus helping the bone to knit together.

[0029] The use of x-rays is practically reduced to the follow-up stage, without the need for radiation while the screw is being implanted and, consequently, without said radiation affecting the surgeon's hands.

[0030] The special configuration of the nail and the manner in which it is assembled enable it to be implanted in the bone by pressure using a suitable nail driver, rather than the classic hammering methods.